

Butler, Jennie C

From: blehrfeld@swankin-turner.com
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Comments of Citizens For Health
"How to Use Health Claims and Nutrient Content Claims in Food Labeling"
Docket #99N-0554
May 11, 1999

Citizens For Health, the consumer voice of the natural health community, brings a special perspective to food nutrient content claims. It strongly urges FDA to encourage the broadest possible availability of health benefit information on the labels of dietary supplements as the primary way to ensure that consumers get the widest choice of the safest nutrients available in the market.

Citizens For Health is the only national organization representing consumers on issues of choice, information and access to natural health products and therapies. Through our nationwide network of community-based chapters, Citizens marshaled more than one million consumer signatures and conducted a three-year campaign for passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Our collaborative 1998 campaign with the organic foods community to "Keep 'Organic' Organic" resulted in over 300,000 letters to USDA protesting its efforts to change the meaning of "organic." And most recently, Citizens organized the "Write to Know" Campaign, generating over 175,000 comments, in the months of September and October of 1998, opposing FDA's proposed change of the definition of disease designed to restrict information available to consumers on product labels.

Citizens For Health was also co-plaintiff in the original 1994 lawsuit and the subsequent appeal of *Pearson v. Shalala*, which successfully challenged the constitutionality of the "significant scientific agreement" standard as FDA had interpreted it through regulation for NLEA: considering only what amounts to "scientific evidence beyond a reasonable doubt" before it approves health claims for dietary supplements.

With interest in dietary supplements crossing age, racial, economic, and educational divisions, consumers are demanding more opportunities to inform themselves about the health benefits of supplements. Expanding the use of health claims is an important aspect of fulfilling the Congressional and public intent in passage of DSHEA. Consumers want the opportunity to take control of their own health. The public has shown time again with their dollars and their voices that they want to use dietary supplements and that they are willing to fight for the right to make informed health choices.

FDA's continued insistence on banning health claims that are generally accepted by the scientific community until they are conclusively proven to a standard virtually indistinguishable from that required of a new drug has had unacceptable consequences on consumer health. Such action led to the deplorable situation where FDA's failure to approve widely accepted scientific claims for folic acid's prevention of birth defects may have led to as many as 2,500 children suffering damage that could have been prevented through consumption of folic acid.

The Presidential Commission on Dietary Supplement Labels, mandated by DSHEA, has also challenged the FDA's narrow interpretation of "significant scientific agreement." The Commission statement included:

ò "the standard of scientific agreement should not be so strictly interpreted as to require unanimous or near-unanimous support"

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ò "FDA should ensure that broad input is obtained to ascertain the degree of scientific agreement that exists for a particular health claim" and "the use of appropriate panels of qualified scientists from outside the agency is encouraged"

ò "that consumer understanding of nutritional support and health claims are important aspects of the information that require additional and continued assessment"

The FDA Reform bill passed in November 1997 expanded the assessment of what health claims might be allowed, and allows health claims to be made on dietary supplement labels if a scientific body of the federal government, like NIH or CDC, has published an "authoritative statement" on the nutrient-disease relationship on which the claim is based.

However, this provision does not make real advances in allowing health claims, because FDA continues to have the final word on approving the applications for health claims on labels. Additionally, FDA still must define its "significant scientific agreement" standard for the health claim applications that have not been addressed by a "scientific body" of the federal government.

Citizens urges that the agency immediately address the definition of "significant scientific agreement" as ordered by the U.S. Court of Appeals in its ruling in *Pearson v. Shalala* and that it bypass its opportunity to seek review by the Supreme Court.

Additionally, Citizens believes that the use of disclaimers, such as those considered by the Appeals Court in the *Pearson v. Shalala* case, should be considered in determining what requirements should apply to health claims based on "authoritative statements."

Citizens urges the overarching policy that the full, robust flow of information is the best way to create both safety and choice for the consumer. In every instance in which FDA looks at a health statement on a label it should expand the opportunity for information to be made available to the consumer.

In summary:

FDA should permit on labels statements that are supported by "significant scientific agreement," including but not limited to "authoritative statements," even if they are preliminary suggestions about possible health benefits, as long as their nature is indicated.

The FDA should bypass its opportunity to seek review of *Pearson v. Shalala* and immediately begin the process of defining "significant scientific agreement" in accordance with the directions of the Appeals Court.

Similarly, the FDA should begin the development of the process of establishing guidelines for the use of disclaimers as suggested by the Appeals Court in *Pearson v. Shalala*.